

## **REMARKS**

Claims 43 to 59, and new claims 60-76 are pending in the present application after entry of the present amendments. Claims 43 and 45 have been amended to more particularly point out and distinctly claim the treatment of metastatic melanoma, with the proviso that gene therapy is not used. The amendments are supported by the specification at *p.26, ll 22 to p.32, ll 12*. In addition, methods for preventing metastatic melanoma are captured in new claims 60 to 76. The new claims are supported by the originally filed specification and claims, *e.g., see p.1, ll. 5-7; p. 4, ll. 2-4, ll. 12-16; p.15, ll. 9-13; p. 17, ll. 23-p. 18, ll. 4; p. 24, ll. 16-17; p. 38, ll. 23-26; and p. 39, ll. 11-14, ll. 26-28*. Accordingly, the amendments are fully supported by the specification and do not introduce any new matter. Applicants respectfully submit that the pending claims are in condition for allowance.

### **I. INTERVIEW SUMMARY**

Applicants are grateful for the telephonic interview dated May 9, 2008, between Examiner Canella and Applicants' representatives, during which proposed amendments to the claims and addition of new claims have been discussed. During the interview, the undersigned pointed out that the proposed amendments address the only two remaining issues in this case, in that they: (i) exclude gene therapy; and (ii) define the target patient population for prevention of metastatic melanoma. The Examiner has indicated that she was favorably impressed and encouraged Applicants to pursue the proposed amendments and new claims.

### **II. THE AMENDED CLAIMS ARE ENABLED UNDER 35 U.S.C. § 112**

The Applicants note with appreciation that all art-based rejections have been withdrawn in view of the previous amendment filed January 14, 2008. The Applicants believe that the remaining rejections under 35 U.S.C. § 112 are obviated by the present amendment.

#### **(A) The treatment of cancers by administration of nucleic acids**

Acknowledging that the claims are enabled for methods for treating metastatic melanoma by selectively antagonizing the endothelin B receptor (ETB), the Examiner alleges, however, that to the extent that the claims read on gene therapy, they are not enabled (p.3 of the Office Action).

In order to expedite prosecution, gene therapy has been excluded from the claims, without prejudice to Applicants' rights to prosecute the canceled subject matter in other

applications. Thus, rejection of claims 43-59 has been obviated and the rejection under 35 U.S.C. §112, first paragraph should be withdrawn.

**(B) Preventing the development of a melanocyte into melanoma in a patient**

With respect to the claim limitation “preventing development of a melanocyte to primary melanoma”, the Examiner alleges that such limitation encompass the prevention of melanoma in a patient who has never had melanoma. This rejection is obviated by the amended claims which no longer recite such limitation. Thus, rejection of claims 43-59 under 35 U.S.C. §112, first paragraph should be withdrawn.

New claims 60-76 recite methods for preventing **metastatic** melanoma in a patient suffering from or diagnosed with melanoma. These claims also exclude gene therapy. Applicants believe that the new claims address the Examiner’s concern (p.4 of the Office Action). As such, new claims 60-76 satisfy all conditions for patentability and are in condition for allowance.

For the foregoing reasons, Applicants respectfully request that the claim rejections under 35 U.S.C. §112, first paragraph, be withdrawn.

**CONCLUSION**

Applicants respectfully request that the amendments and remarks made herein be entered and made of record in the file history of the present application. Withdrawal of the rejections in the previous Office Action and a notice of allowance are earnestly requested. Applicants respectfully submit that the pending claims are in condition for allowance. If any issues remain in connection herewith, the Examiner is respectfully invited to telephone the undersigned to discuss the same.

Respectfully submitted,

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